

REMARKS

Claims 1-38 are pending.

The Examiner has withdrawn the prior restriction requirement and has issued a new restriction requirement under 35 U.S.C. § 121 between claims 1-34 and 35-38. Claims 35-38 have been withdrawn from consideration. Applicants accept the modified restriction requirement without prejudice to their right to prosecution of Claims 35-38 in a divisional application.

Claims 1-17 and 26-34 have been rejected as allegedly anticipated under 35 U.S.C. § 102(b) over U.S. Patent No. 6,255,487 to Duchene et al. ("*Duchene*"). Claims 1-21 and 26-34 have been rejected as allegedly anticipated under 35 U.S.C. § 102(e) over WO 2004/103982 to Singh et al. ("*Singh*"). Claims 22-25 have been rejected as allegedly obvious under 35 U.S.C. § 103(a) over *Singh* in view of secondary references. Claims 18-19 have been rejected as allegedly anticipated under 35 U.S.C. § 102(b) over U.S. Patent No. 4,525,358 to Baltes et al. ("*Baltes*"). Claims 9-17 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Claim 28 has been objected to.

By this Amendment, Claims 9, 18-25 and 28 have been amended. Applicants respectfully request reconsideration and allowance of all pending claims.

I. REJECTION OVER *DUCHENE*

The Examiner has rejected claims 1-17 and 26-34 as anticipated by *Duchene*. According to the Examiner, *Duchene*'s Example IV.1.2 describes a white solid identical to the monohydrochloride salt of cetirizine hydrochloride claimed in the present patent application. The Examiner appears to suggest that Example IV.1.2 of *Duchene* inherently anticipates claimed monohydrochloride salt of cetirizine.

Applicants decidedly and respectfully disagree.

First, *Duchene* is explicit with respect to the identity of the white solid produced in Example IV.1.2. It is described with specificity as free base of cetirizine. See col. 19, lines 46-47 ("5.6g (48.5% of 2-[2-4-[(4-chlorophenyl)phenylmethyl]-1-piperazinyl]ethoxy]acetic acid . . ."). The described chemical name does not identify a

salt under well-accepted rules of nomenclature and thus clearly and specifically identifies the solid as cetirizine free base. Does the Examiner believe that Example IV.1.2. of *Duchene* produces a salt regardless of the clear identification of the product as a free base, or the Examiner believes that the *Duchene* inventors failed to differentiate between the two? In this regard, Applicants respectfully direct Examiner's attention to Example III.1B of *Duchene*. See col. 18, line 26 ("2-(4-benzyl-1-piperazinyl) ethoxyacetic acid **dihydrochloride** .."). When the *Duchene* inventors wished to identify material as a salt, they did so unambiguously. *Duchene* explicitly teaches a free base. On this ground alone, *Duchene* simply does not satisfy the requirements for inherent anticipation.

Second, to establish inherent anticipation, the Examiner must show a scientific rationale or objective evidence tending to show inherency. See MPEP §2112. In particular, the reference's teachings or extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and it would be so recognized by persons of ordinary skill." See *id.*, citing *In re Robertson*, 49 U.S.P.Q.2d (BNA) 1949, 1950-51 (Fed. Cir. 1999). How can the "necessarily present" standard be satisfied in view of *Duchene*'s explicit teaching to the contrary? What would be the objective evidence of inherency in view of this teaching?

Moreover, the standard for recognition by one skilled in the art cannot be met under the facts. To advance prosecution, Applicants submit herewith an affidavit from Mr. N. Murthy, a scientist with 13 years of experience in pharmaceutical industry, including 10 year experience in pharmaceutical solids. It is submitted that Mr. Murthy clearly satisfies the criteria for one skilled in the art. As seen from the attached affidavit, one skilled in the art (*i.e.*, Mr. N. Murthy) clearly does not recognize that the missing descriptive matter is "necessarily present," as required under the law. See *id.* Moreover, the attached affidavit shows that the combination of objective evidence and scientific reasoning suggest to an artisan that the white solid produced in Example IV.1.2 of *Duchene* was cetirizine free base. The attached affidavit is now an uncontroverted evidence of record.

The totality of evidence of record clearly indicates that the solid disclosed in *Duchene* is not identical to claimed salt of cetirizine.

Withdrawal of the anticipation rejection over *Duchene* is respectfully requested.

II. REJECTIONS OVER *SINGH*

The Examiner has made rejections over *Singh*, which is alleged to qualify as a reference under 35 U.S.C. § 102(e). The Examiner specifically cited MPEP §201.15, which addresses a situation when there exist a prior art reference with a date of priority between the date of foreign filing and the date of filing in the United States. In accordance with MPEP §201.15, Applicants hereby respectfully direct the Examiner's attention to Indian Patent Application Number 252/MAS/2003, for which the benefit of priority is properly claimed in the present patent application under 35 U.S.C. § 119. A valid claim for priority, including a certified copy of the Indian application, was filed with paper of April 7, 2007, a copy of which is attached herewith for immediate reference of the Examiner. Thus, the effective priority date of present application is March 25, 2003 (the filing date of Indian Patent Application Number 252/MAS/2003), which is before the prior art date of WO 2004/103982 (May 21, 2003).

Withdrawal of all rejections over *Singh* is respectfully requested.

III. OTHER OBJECTIONS/REJECTIONS

Claims 18 and 19 have been rejected over *Baltes*. In response, Applicants amended claim 18 as suggested by the Examiner. Applicants submit that the rejection has been overcome.


Claims 9-17 have been rejected for lack of recitation of a carrier in claims to a composition. Respectfully, Applicants do not agree with the Examiner's conclusion of indefiniteness. However, to advance prosecution and in view of lack of effect on the scope of the claims, Applicants amended claims 9-17. Applicants submit that the rejection has been overcome.

Claim 28 has been objected to. Applicants amended claim 28 as suggested by the Examiner. Applicants submit that the rejection has been overcome.

In view of the foregoing, the Applicants submit that all claims are in condition for allowance. Accordingly, both reconsideration of this application and its swift passage to issuance are earnestly solicited. In the event that there are any fees dues and owing in connection with this matter, please charge the same to our Deposit Account No. 50-3221.

Respectfully submitted,

Dated: October 2, 2007

By: 
Milagros A. Cepeda
Reg. No. 33,365

Dr. Reddy's Laboratories, Inc.
200 Somerset Corp. Blvd.
Bridgewater, NJ 08807

Tel: (908) 203-6505
Fax: (908) 203-4970
mcepeda@drreddys.com